

NORTH CAROLINA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Item 2435 - Board Elections for the Western and Northern District Seats Underway

The North Carolina Board of Pharmacy is conducting an election to fill two positions in the Northern and Western Districts. North Carolina pharmacists may vote anytime between now and March 1, 2022. Log in to your pharmacist profile through the Licensure Gateway and select the yellow "Election - Northern & Western Districts" tile. There you may read about the candidates before casting your votes.

All pharmacists actively licensed and living in North Carolina as of October 31, 2021, are eligible to vote. The winners of this election will begin their terms on May 1, 2022.

- Northern District candidate information: www.ncboporgelection2021NorthernDistrictCandidates
 .html
- Western District candidate information: www.ncbop.org/election2021WesternDistrictCandidates
 .html

Item 2436 – Board Revises Process for Approval of Pharmacist-to-Technician Ratio Requests

North Carolina Pharmacy Practice Act General Statute (GS) 90-85.15A(c) states that "a pharmacist may not supervise more than two pharmacy technicians unless the pharmacist-manager receives written approval from the Board. The Board may not allow a pharmacist to supervise more than two pharmacy technicians unless the additional pharmacy technicians are certified pharmacy technicians." In light of changes to the North Carolina Pharmacy Practice Act granting qualified pharmacy technicians the authority to administer certain vaccines under pharmacist supervision and the expansion of pharmacists' ability to initiate and modify certain drug therapies, effective February 1, 2022, the Board has modified its process for reviewing and approving pharmacist-to-technician ratio requests.

A pharmacist-manager's request for a 1:3, 1:4, or 1:5 pharmacist-to-technician ratio may be allowed by Board staff without formal Board action as long as the pharmacist-manager demonstrates that the pharmacy employs a sufficient number of certified technicians to meet the ratio. A pharmacist-manager's request for a 1:6 or higher pharmacist-to-technician ratio must be considered by the full Board.

More detail on the Board's revised process, as well as instructions on how to submit a pharmacist-to-technician ratio request, can be found here.

Item 2437 – DEA Issues Notice of Proposed Rulemaking Concerning Transfers of Electronic CS Prescriptions

Pharmacists may recall that, in 2017, then-Drug Enforcement Administration (DEA) Associate Section Chief Loren Miller stated in an email that unfilled prescriptions for controlled substances (CS) of any schedule could not be transferred among pharmacies for initial dispensing. The email described a DEA policy that an unfilled electronic prescription for a CS could be "forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy." However, the email did not provide any guidance as to how an unfilled electronic prescription should be "forwarded," or what documentation was required. DEA's policy-by-email announcement also created several other practical problems. More details are available here.

On November 19, 2021, DEA published a proposed rule governing the transfer of electronic prescriptions for Schedules II-V CS between pharmacies for initial filling. In it, DEA acknowledges some of the challenges that its 2017 statement created for patients, prescribers, and pharmacists – including the potential for duplication of CS prescriptions and significant procedural burdens on patients and pharmacies.

The proposed rule would allow pharmacies a one-time transfer of an unfilled electronic prescription to another pharmacy for initial dispensing. The proposal's preamble claims that there is no concern where paper prescriptions are involved because a pharmacy may return the paper prescription to the patient for dispensing at another pharmacy. The proposal is silent about the transfer of valid, unfilled verbal prescriptions for CS, even though the concerns that DEA identifies with its current policy regarding electronic prescriptions are precisely the same (ie, the patient has no physical copy of the prescription and, therefore, cannot take it to another pharmacy for filling; there is a risk of duplicate CS prescriptions at multiple pharmacies; and procedural burdens on patients and pharmacies).

The proposed rule states that the prescription "must be transferred from one retail pharmacy to another retail pharmacy in its electronic form" and that "[a]t no time may an intermediary convert an electronic prescription to another form (e.g., facsimile) for transmission." It further warns that "any change to the content during transfer, including truncation or removal of data, will render the electronic prescription invalid." Board staff is concerned that these requirements may be achievable when an electronic prescription is transferred among pharmacies sharing a common, real-time database, but will be impossible to meet when a transfer among pharmacies that do not share such a database is contemplated (which is likely to be a substantial portion of transfers).

The proposed rule requires that transfers be "communicated directly between two licensed pharmacists" and specifies various information that must be recorded in the electronic prescription record by the transferring and recipient pharmacists.

DEA is accepting written and electronic comments on the proposed rule on or before January 18, 2022. The notice of rulemaking provides instructions on comment submission. Pharmacists are strongly encouraged to review the proposal and provide comments to DEA.

Item 2438 – Board Publishes Proposed New Rules and Amendments to Existing Rules Concerning Remote Work by Pharmacy Personnel, Pharmacist-Manager Education, and Pharmacy Intern Status

The Board has published for notice and comment a new rule and several amendments to existing rules. Members of the public are invited to comment on these proposals. The comment period runs through February 14, 2022, and a public hearing on each proposed action will occur February 8, 2022. Instructions on submitting comments are available here.

Remote Work by Pharmacy Personnel

During the coronavirus disease 2019 (COVID-19) public health emergency, North Carolina pharmacy personnel have been able to perform certain work outside of the pharmacy under a Board of Pharmacy Emergency Services Waiver. Further, some other states' laws permit pharmacy personnel to perform remote work. During a recent notice and comment period for other Board rules, many commenters requested that the Board adopt the proposed rule to provide for permitted pharmacy locations in North Carolina to allow remote work (other than physical acts in the dispensing process) on a permanent basis and to approve out-of-state permitted pharmacy locations to provide similar services for North Carolina patients to the extent permitted by their home states. The Board believes that the proposed rule will permit alternative work environments while maintaining processes and systems for patient safety.

Pharmacist-Manager Education and New Permit Process

Current rules require the pharmacist-manager for each permit applicant to meet personally with Board staff before the Board will grant a permit. These meetings have traditionally been a means of imparting knowledge about North Carolina pharmacy law and Board procedures. These meetings are an inefficient way to provide that information, and the result of this burden has been that out-of-state permit applicants often have not named their actual pharmacist-manager as the pharmacist-manager on their North Carolina applications, thereby creating a disconnect between the person who is legally responsible for their compliance with North Carolina law and the person who actually supervises the pharmacy. The principal purposes of the proposed changes are to substitute an online educational module in place of the in-person meeting and to require that the pharmacist-manager on the North Carolina permit matches the pharmacist-manager in the pharmacy's home state.

Pharmacy Interns

The Pharmacy Practice Act requires all applicants for initial licensure and certain reinstatement and reciprocity candidates to complete practical experience to be licensed, and further requires the Board to adopt regulations to "assure that the person successfully completing the program will have gained practical experience that will enable him to safely and properly practice pharmacy." See GS 90-85.14. Those gaining practical experience are regularly and collectively referred to as "pharmacy interns." The Board has proposed to amend 21 North Carolina Administrative Code 46.1503 to provide for a uniform system by which those gaining practical experience can sign up with the Board and easily document and verify their

practical experience hours through an online system. Moreover, in recent years, a handful of individuals have falsely claimed to be pharmacy students or recent graduates who were entitled to work as pharmacy interns, and therefore, allowed to engage in all acts constituting the practice of pharmacy under the supervision of pharmacists. These individuals who lacked pharmacy educational training thereby created a risk of harm to the public safety, health, and welfare to defraud their employers. The new uniform system will make it easier to ensure that only those who are entitled to work as pharmacy interns are able to do so.

Item 2439 – Follow the Board Website for Continual Updates on COVID-19-Related Matters, Including Vaccination Process and Authority

Staff continue to frequently update the Board website on general COVID-19-related matters and specifically on COVID-19 vaccination matters. Updates are posted on the home page of the website, then periodically consolidated in a general COVID-19 updates section and a COVID-19 vaccination-related updates and resources section. Key updates are

National Pharmacy Compliance News Now Available!

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

Read National News

also included in a weekly email to all pharmacists.

The North Carolina Board of Pharmacy News is published by the North Carolina Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Jack W. "Jay" Campbell IV, JD, RPh - State News Editor

Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Amy Sanchez - Publications and Editorial Manager

6015 Farrington Rd, Suite 201 | Chapel Hill, NC 27517 | 919/246-1050 | Fax: 919/246-1056 | www.ncbop.org